

## **REMARKS**

Reconsideration and withdrawal of the rejections of this application and consideration and entry of this paper are respectfully requested in view of the herein remarks and accompanying information, which place the application in condition for allowance.

### **1. Status Of Claims And Formal Matters**

Claims 1-72 are under consideration in this application. Claims 1, 10, 11-13, 14, 16 and 17 have been amended and claims 9, 15 and 34-72 have been canceled. No new matter has been added by this amendment.

Support for the recitation of an intein is a truncated Mtu intein with the endonuclease domain deleted, and V67L and/or D422G mutation(s) or any intein having a D to G mutation in a location corresponding to residue 422 of the full-length Mtu intein, by sequence homology or any intein having a V to L mutation in a location corresponding to residue 67 of the full-length Mtu intein, by sequence homology is found in claim 15 as originally filed.

Claims 1, 10-13, 14, 16 and 17 have been amended without prejudice, without admission, and without surrender of subject matter, and without any intention of creating any estoppel as to equivalents to recite the base claim and intervening claims.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited by the Examiner, and that these claims were in full compliance with the requirements of 35 U.S.C. § 112. The amendments of the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

### **2. The Objections to the Claims Are Overcome**

Claims 11-33 were objected to as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. Claim 15 has been canceled, thereby obviating the objection in part. Claims 11-13, 14, 16 and 17 have been clarified to depend from claim 1, thereby obviating the objection. Since claims 18, 20, 24 and 26-31 depend from claim 17, the objection to claims 18, 20, 24 and 26-31 are also obviated. Since claim 19 depends from claim 18, which depends from claim 17, the objection to claim 19 is also obviated.

Since claims 21-23 and 25 depend from claim 20, which depends from claim 17, the objections to claims 21-23 and 25 are also obviated. Since claim 32 depends from claim 16, the objection to claim 32 is also obviated. Since claim 33 depends from claim 32, which depends from claim 16, the objection to claim 33 is also obviated.

It is believed that the objections have been overcome. Reconsideration and withdrawal are requested.

**5. The Rejections Under 35 U.S.C. § 112, First Paragraph, Are Overcome**

Claims 1-10 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is respectfully traversed. This rejection is moot in light of the amendments to the claims submitted herein.

The Examiner contends that the specification and claims do not indicate what distinguishing attributes are shared by the members of the genus, i.e., the specification allegedly fails to describe the common attributes or characteristics that identify members of the highly variant genus. The Examiner also alleges that adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it, specifically that the protein itself is required.

Although the Applicants do not agree with the Examiner, in the interest of expediting prosecution, claim 1 has been amended to insert the claim limitation of claim 15. Specifically, claim 1 has been amended to recite that the intein is a truncated Mtu intein with the endonuclease domain deleted, and V67L and/or D422G mutation(s) or any intein having a D to G mutation in a location corresponding to residue 422 of the full-length Mtu intein, by sequence homology or any intein having a V to L mutation in a location corresponding to residue 67 of the full-length Mtu intein, by sequence homology. The intein of amended claim 1 was isolated from the screening method described in the specification as originally filed (see, e.g., page 23, line 15 to page 24, line 30).

Claim 9 has been canceled, thereby obviating the rejection in part. Since claims 2-8 and 10 depend from claim 1, the rejection of claims 2-8 and 10 are also obviated.

It is believed that the rejections under 35 U.S.C. § 112, first paragraph, have been overcome. Reconsideration and withdrawal are requested.

**5. The Rejections Under 35 U.S.C. § 102(e) Are Overcome**

Claims 1-3 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by Comb *et al.* (U.S. Patent No. 5,834,247, hereinafter “Comb”). This rejection is respectfully traversed. This rejection is moot in light of the amendments to the claims submitted herein. The cited reference does not anticipate the instant invention.

The instant invention relates to a non-naturally occurring intein or cleavage or cleavage and splicing moiety having splicing activity and/or controllable cleavage activity. In particular, the instant invention relates to a truncated Mtu intein with the endonuclease domain deleted, and V67L and/or D422G mutation(s) or any intein having a D to G mutation in a location corresponding to residue 422 of the full-length Mtu intein, by sequence homology or any intein having a V to L mutation in a location corresponding to residue 67 of the full-length Mtu intein, by sequence homology. The intein of the present invention is not disclosed, suggested or enabled by Comb.

It is respectfully pointed out that a two-prong inquiry must be satisfied in order for a Section 102 rejection to stand. First, the prior art reference must contain all of the elements of the claimed invention. *See Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Second, the prior art must contain an enabling disclosure. *See Chester v. Miller*, 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990). A reference contains an enabling disclosure if a person of ordinary skill in the art could have combined the description of the invention in the prior art reference with his own knowledge of the art to have placed himself in possession of the invention. *See In re Donohue*, 226, U.S.P.Q. 619, 621 (Fed. Cir. 1985).

Applying the law to the instant facts, the reference relied upon by the Office Action does not disclose, suggest or enable Applicants' invention. Comb does not teach, suggest or enable a truncated Mtu intein with the endonuclease domain deleted, and V67L and/or D422G mutation(s) or any intein having a D to G mutation in a location corresponding to residue 422 of the full-length Mtu intein, by sequence homology or any intein having a V to L mutation in a location corresponding to residue 67 of the full-length Mtu intein, by sequence homology.

Comb does not teach, suggest or enable any D (aspartic acid) to G (glycine) or V (valine) to L (leucine) mutations. The only substitution mutations that Comb illustrates are (1) a single amino acid change at the serine 1082 of CIVPS2 (col. 11, line 31-33), (2) amino acid substitutions for the threonine 1472 residue of CIVPS2 (col. 11, lines 49-53), (3) an arginine substitution at position 1079 of CIVPS2 (col. 12, lines 40-43), and (4) an alanine substitution for the aspartate 1236 residue (col. 13, lines 54-57). Thus, Comb does not contain all of the elements of the presently claimed invention.

Consequently, reconsideration and withdrawal of the Section 102 rejections are earnestly requested.

**REQUEST FOR INTERVIEW**

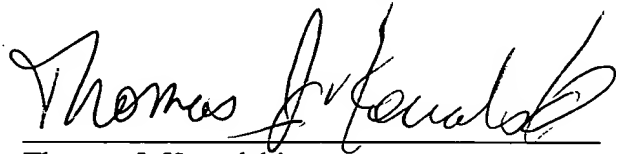
If any issue remains as an impediment to allowance, a further interview with the Examiner and SPE are respectfully requested; and, the Examiner is additionally requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

**CONCLUSION**

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution. The Commission is authorized to charge any fee occasioned by this paper, or credit any overpayment of such fees, to Deposit Account No. 50-0320.

Respectfully submitted,  
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